

## REMARKS

### Priority

The Examiner stated that the instant application cannot claim the benefit of priority of an earlier application 09/260,743, filed March 1, 1999, because the prior application has been abandoned. Applicants submit that a petition of revival was granted in a letter mailed from the Patent Office on February 20, 2003 (enclosed). Hence, Applicants submit that the effective filing date of the instant application is March 1, 1999.

### Oath/Declaration

Applicants hereby submit a new combined declaration and power of attorney in compliance with 37 C.F.R. 1.67(a).

### Specification

The Cross-Reference To Related Application in the specification was objected to for lack of copendency with prior application. As indicated above, Applicants submit that the prior application was revived and thus the copendency requirement has been satisfied.

The specification has also been amended to capitalize trademarks mentioned herein.

#### Claim Objection

Claims 17-20 were objected to. The objection is moot because claims 17-20 have been canceled.

#### The 35 USC §112 Rejections

Claims 1-16 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The rejection is respectfully traversed.

Claims 1-14 have been canceled. Applicants submit that claims 15 and 16 have been amended to recite elements with sufficient antecedent basis to obviate the indefinite rejection.

Claim 15 (a) has been amended to recite “a dry solid support matrix”. Claim 15 (c) has been amended to recite “blotting said sponge containing said sample sorbed thereon onto a specimen circle of said storage card”. Claim 15 (d) has been amended to recite air-drying said affixed sample on said dry solid support matrix wherein the dry solid support matrix comprises a compound or composition that reduces the risk of contamination and degradation

of the affixed sample. Claim 15 (f) has been amended to recite placing the storage card containing said affixed sample into the resealable storage pouch. Original claim 15 (j) has been amended to recite placing said sealed storage pouch into said labeled storage folder. Original claim 15 (k) has been amended to delete the rejected phrase “the sample affixed to the dry solid support”.

Claim 16 has been amended to recite repeating steps (a) to (c) of claim 15 until all of the specimen circles on said storage card contain a non-blood sample affixed thereto.

In view of these amendments, Applicants respectfully request that the rejections of claims 15-16 under 35 U.S.C. §112, second paragraph, be withdrawn.

#### The 35 USC §102 Rejections

Claims 17-19 were rejected under 35 USC §102(b) as anticipated by **Quattrochi** (U.S. Patent 5,978,466), in light of Roget’s Interactive thesaurus. The rejection is moot because claims 17-19 have been canceled.

Claim 20 was rejected under 35 USC §102(b) as anticipated by **Quattrochi** (U.S. Patent 5,978,466) in light of Roget’s

Interactive thesaurus and the teaching of **Turner** (U.S. Patent 5,211,286). The rejection is moot because claims 17-19 have been canceled.

#### The 35 USC §103(a) Rejections

Claims 1-6 and 14 were rejected under 35 USC §103(a) as being unpatentable over **Burgoyne** (U.S. Patent 5,972,386) in view of **Quattrochi** (U.S. Patent 5,978,466). The rejection is moot because claims 1-6 and 14 have been canceled.

Claim 13 was rejected under 35 USC §103(a) as being unpatentable over **Burgoyne** in view of **Quattrochi**, in light of Roget's Interactive thesaurus. The rejection is moot because claim 13 has been canceled.

Claims 7-9 were rejected under 35 USC §103(a) as being unpatentable over **Burgoyne** in view of **Quattrochi**, and further in view of **Tess et al.** The rejection is moot because claims 7-9 have been canceled.

Claims 10-12 were rejected under 35 USC §103(a) as being unpatentable over **Burgoyne** in view of **Quattrochi**, and further in view of **Haas et al.** (U.S. Patent 5,862,101). The rejection is moot because claims 10-12 have been canceled.

Claim 13 was rejected under 35 USC §103(a) as being unpatentable over **Burgoyne** in view of **Quattrochi**, and further in view of **Biddle et al.** (U.S. Patent 5,492,268). The rejection is moot because claim 13 have been canceled.

Claims 15-16 were rejected under 35 USC §103(a) as being unpatentable over **Burgoyne** in view of **Quattrochi** and **Tess et al.**, and further in view of **Hass et al.**, in light of Roget. This rejection is respectfully traversed.

**Burgoyne** teaches a dry solid medium and method for collection of genetic material in a form suitable for storage or subsequent analysis. **Quattrochi** teaches a method of detecting HIV infection in which samples are self-collected, packaged and mailed to a testing site. **Tess et al.** teach a method of collecting oral fluid samples. **Hass et al.** teach a tamper indicating packaging tape.

The Examiner acknowledges that **Burgoyne** and **Quattrochi** do not teach a method that involves swabbing the inside of the mouth of a subject with a sponge to obtain a non-blood sample as claimed herein. The Examiner contends, however, in view of **Tess et al.**, it would have been obvious to modify the method of **Burgoyne** and **Quattrochi** so as to collect oral fluid samples using a sponge. Applicants respectfully disagree.

Applicants submit that **Tess et al.** do not teach or suggest swabbing the inside of the mouth to obtain a non-blood sample for genetic analysis as claimed herein. **Tess et al.** only teach collecting salivary samples to detect anti-HIV antibodies (see abstract and “Testing of oral fluid samples” under MATERIAL AND METHODS on page 788). **Tess et al.** do not teach or suggest collecting salivary samples for DNA or RNA analysis. Therefore, **Tess et al.** do not provide any motivation to a person having ordinary skill in this art to combine with **Burgoyne** and **Quattrochi** so as to collect non-blood samples for DNA analysis as claimed herein. Neither do **Tess et al.** provide any reasonable expectation of success in obtaining salivary samples for DNA analysis because collecting samples for DNA analysis is simply out of the scope of the teaching of **Tess et al.**

Moreover, **Tess et al.** do not teach or suggest swabbing the inside of the mouth to obtain a sample as claimed herein. **Tess et al.** only teach rubbing a soft sponge foam swab along the junction of the teeth and gums for 1 minute so as to saturate the sponge with saliva (see "Collection of oral fluid samples" under MATERIAL AND METHODS on page 788). Swabbing the inside of the mouth is clearly distinguishable from rubbing on the gums for one minute because one of ordinary skill in the art would readily realize that rubbing and soaking for one minute is not swabbing. One of skill in the art would readily comprehend swabbing in the context of collecting oral samples as a quick and brief procedure that does not entail rubbing and soaking with saliva for at least 1 minutes. **Tess et al.** only teach collecting saliva that requires rubbing and soaking the sponge for 1 minute, whereas the instant invention only requires a brief step of swabbing to collect oral cell samples. Hence, **Tess et al.** do not teach or suggest a method of obtaining oral samples for DNA analysis, which is a critical element of the instant invention.

The Examiner also rejects other steps of the instant invention such as the use of storage pouch, sealing with security tape and storage with a folder etc. To establish a *prima facie* case of obviousness, however, requires the combined teaching of the prior

art teach or suggest all the limitations of the claimed invention. As discussed above, the reference (**Tess et al.**) relied upon by the Examiner to supply the element of collecting oral samples does not teach or suggest collecting oral samples for DNA analysis as claimed herein. Therefore, the combined teaching of the prior art cited by the Examiner does not teach or suggest all the limitations of the instant invention.

In view of the above remarks, the combined teaching of **Burgoyne**, **Quattrochi**, **Tess et al.**, **Hass et al.**, and **Roget** does not provide a person having ordinary skill in this art with the requisite expectation of successfully producing Applicants' claimed method. The invention of collecting and storing oral samples for DNA analysis as a whole is not *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Accordingly, Applicants respectfully request that the rejection of claims 15-16 under 35 U.S.C. §103(a) be withdrawn.

Claims 15-20 were rejected under 35 USC §103(a) as being unpatentable over **Burgoyne** in view of **Quattrochi** and **Tess et al.**, and further in view of **Hass et al.** and **Biddle et al.** This rejection is respectfully traversed.



Applicants submit that the Examiner essentially relies on the same basic argument as described above (in the rejection of claims 15-16) to reject claims 15-20. Hence, Applicants submit the same counter argument as described above. Applicants reiterate that the combined teaching of the prior art cited by the Examiner does not teach or suggest all the limitations of the instant invention. The reference (Tess *et al.*) relied upon by the Examiner to supply the element of collecting oral samples does not teach or suggest collecting oral samples for DNA analysis as claimed herein. Therefore, the combined teaching of **Burgoyne**, **Quattrochi**, **Tess et al.**, **Hass et al.** and **Biddle et al.** does not provide a person having ordinary skill in this art with the requisite expectation of successfully producing Applicants' claimed methods. The invention as a whole is not *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Accordingly, Applicants respectfully request that the rejection of claims 15-20 under 35 U.S.C. §103(a) be withdrawn.

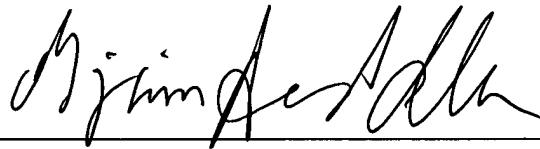
This is intended to be a complete response to the Office Action mailed February 13, 2003. If any issues remain outstanding,

the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

DATE:

May 19, 2003

A handwritten signature in black ink, appearing to read "Benjamin A. Adler", written over a horizontal line.

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